NOT FOR PUBLICATION (Docket No. 13)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

SHERRY APPLEBY,	:	
Plaintiff,	:	Civil No. 04-0062 (RBK)
v.	:	**OPINION**
GLAXO WELLCOME, INC., a North Carolina Corporation, et al.,	:	
Defendants.	:	

KUGLER, United States District Judge:

In this pharmaceutical product liability case, Plaintiff Sherry Appleby ("Plaintiff") brings claims against defendant SmithKline Beecham Corporation d/b/a/ GlaxoSmithKline ("GSK"), the manufacturer of Lotronex®, a prescription drug she ingested for several months to treat irritable bowel syndrome ("IBS"). Plaintiff alleges medical complications resulting in hospitalization on November 27, 2000, related to her consumption of Lotronex®. GSK now moves for summary judgment on all claims.

I. Background

A. Lotronex® and Irritable Bowel Syndrome

The Federal Food and Drug Administration ("FDA") approved Lotronex® as the first prescription drug intended to treat women

with the diarrhea-predominant form of IBS, an illness that causes recurrent abdominal pain, bloating, uncontrollable diarrhea, and/or constipation in approximately 15% of the American population. GSK launched Lotronex® on March 13, 2000, making it available for sale upon prescription by a licensed physician.

By June 1, 2000, the FDA had received adverse event reports of serious outcomes associated with Lotronex®, including constipation and ischemic colitis, and GSK and the FDA began discussing possible Risk Management Plans for Lotronex® use. In August 2000, GSK revised the Lotronex® labeling to highlight the risks associated with the drug and the FDA issued "Dear Health Care Professional" and "Dear Pharmacist" letters.[1] However,

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[1] The package insert for Lotronex® as of the time it was prescribed to the Plaintiff contained the following warnings about constipation:

> WARNINGS:
> Constipation is a frequent and dose-related side effect of treatment with Lotronex®. LOTRONEX should not be used in IBS patients who are currently constipated or whose predominant bowel symptom is constipation. In clinical studies, 25 to 30% of patients receiving alosetron experienced constipation. For the majority of these patients, constipation was mild to moderate in intensity and self-limited; however, approximately 9% of patients required interruption of treatment for a few days and approximately 10% could not tolerate twice daily dosing on a continuous basis and discontinued therapy. Patients experiencing constipation who completed the 12-week treatment period had similar relief of abdominal pain as patients not experiencing constipation who completed the study.

in September 2000, the FDA received the first report of a death associated with the use of Lotronex®, followed by reports of four additional deaths. On November 28, 2000, GSK voluntarily withdrew Lotronex® from the market.

After withdrawing Lotronex®, GSK submitted additional information to the FDA about the safety and efficacy of Lotronex®, and several IBS patients expressed their need for the drug. In response, the FDA re-approved Lotronex® for use in women with severe diarrhea-predominant IBS, returning Lotronex® to the market in November 2002 with considerable restrictions on its distribution and use.

B. Plaintiff Sherry Appleby

On January 17, 2000, Plaintiff visited Dr. Joel E. Krachman, a board-certified gastroenterologist, complaining of rectal bleeding, bloating, and increased flatus. Dr. Krachman diagnosed

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> Management of constipation with usual care, including laxatives, fiber, or a brief interruption of therapy may be considered (see DOSAGE AND ADMINISTRATION).

In addition, the portion of the package insert which pharmacists are instructed to give their patients when they filled prescriptions contained the following warnings:

> What are the possible side effects of Lotronex®? . . . Constipation is a common side effect of treatment with LOTRONEX. If you become constipated while taking LOTRONEX, call your doctor. Your doctor may tell you to stop taking LOTRONEX or suggest other ways to manage your constipation.

her with rectal bleeding and IBS, and prescribed various medications. After these medications failed to relieve Plaintiff's symptoms, Dr. Krachman prescribed Lotronex® on or about March 20, 2000. At a subsequent visit to Dr. Krachman on November 1, 2000, Dr. Krachman noted that Plaintiff had "excellent results with Lotronex®," and that she "understands [the] risks" of constipation. (Dr. Joel E. Krachman Aff., Def.'s Reply Supp. Mot. Summ. J. Ex. B, ("Krachman Aff.").)

On November 29, 2000, Plaintiff was admitted to the Atlantic City Medical Center for severe abdominal pain and ileus, an obstruction of the bowel. Plaintiff first learned of the withdrawal of Lotronex® from the market while she was in the hospital, and has not ingested the drug since November 27, 2000. Since discontinuing Lotronex®, Plaintiff continued to suffer abdominal pain. Plaintiff was again hospitalized with abdominal pain or discomfort on January 9, 2001, January 27, 2001, and April 6, 2001.

Plaintiff filed suit against GSK in the Superior Court of New Jersey on February 4, 2003, and GSK removed the action to this Court on the basis of diversity jurisdiction on January 8, 2004.

II. Standard

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file,

together with the affidavits, if any, show that there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). An issue is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Consolidated Rail Corp., 297 F.3d 242, 247 (3d Cir. 2002) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). The nonmoving party is "entitled to all reasonable inferences and the record is construed in the light most favorable to that party." Anderson, 297 F.3d at 247 (citing Pollock v. American Tel. & Tel. Long Lines, 794 F.2d 860, 864 (3d Cir. 1986)).

Nevertheless, the party opposing a motion for summary judgment "may not rest upon the mere allegations or denials" of his pleading, but "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(c). Where the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," the moving party is entitled to a judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

Where the nonmoving party does not submit undisputed facts in opposition, "it is entirely appropriate for this court to treat all facts properly supported by the movant to be uncontroverted." Talbot v. United States, 2005 WL 2917463, *2 (D.N.J. 2005) (quoting Allebach v. Sherrer, No. 04-287, 2005 U.S.

Dist. LEXIS 15626, at *5 (D.N.J. 2005)). Plaintiff here failed to submit a statement of undisputed material fact, as required by Local Civil Rule 56.1.

III. Evidentiary Challenges

GSK moves to strike several portions of the Certification of Michael J. Pender and attached documents. Specifically, GSK seeks to strike Exhibits A, B, and C which consist of FDA documents of an unspecified nature.[2]

To be considered as evidence in a motion for summary judgment, documents must be properly authenticated in satisfaction of Federal Rule of Evidence 901(a). Shanklin v. Fitzgerald, 397 F.3d 596, 602 (8th Cir. 2005) (affirming district court's exclusion of unauthenticated and inadmissible exhibits on motion for summary judgment); Orr v. Bank of America, NT & SA, 285 F.3d 764, 773 (9th Cir. 2002) (same). Documents can be authenticated by an affidavit of an individual with personal knowledge able to provide evidence "sufficient to support a finding that the matter in question is what its proponent claims." Orr, 285 F.3d at 773 (quoting Fed. R. Evid. 901(a)).[3]

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[2] The Court declines to address the admissibility of Plaintiff's Exhibit F (FDA document "Lotronex Questions and Answers"), Exhibits G and H (the GSK website), Exhibit I (an article from Forbes.com), and Exhibit K (GSK handouts to medical doctors), as they are not relevant to the Court's analysis below.

[3] For example, a public record or report can be authenticated by "[e]vidence that a writing authorized by law to be recorded or filed and in fact recorded or filed in a public

However, the failure to establish that the document is genuine renders the evidence inadmissible. Fed. R. Evid. 901(a).

Here, Plaintiff offers an affidavit by her counsel, Michael J. Pender, a partner of Targan & Pender, P.A. Although Pender claims personal knowledge, nowhere does the affidavit make any statement establishing the genuineness of the documents or indicating that they are true, complete, or correct copies. Rather, the affidavit states only, for example, "Attached hereto as Exhibit A is an FDA document titled 'Gastro Intestinal Drug Advisory Committee' dated April 23, 2002." (Michael J. Pender Aff. at 2.) Plaintiff has thus failed to establish that the documents are what they purport to be.

Moreover, Plaintiff's claim that the documents fall within the hearsay exception for public records and reports is misplaced. Federal Rule of Evidence 803(8) authorizes admission of "factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness." This exception is grounded on assumptions about "the reliability of the public agencies usually conducting the investigation, and 'their lack of any motive for conducting the

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office, or a purported public record, report, statement, or data compilation, in any form, is from the public office where items of this nature are kept." Fed. R. Evid. 901(b)(7).

studies other than to inform the public fairly and adequately.'" Ellis v. International Playtex, Inc., 745 F.2d 292, 300-01 (4th Cir. 1984) (quoting Kehm v. Proctor & Gamble, 724 F.2d 613, at 618, 619 (8th Cir. 1983). Consequently, this presumption typically does not apply to render hearsay admissible where the findings are merely proposed, tentative, or "second-hand." Toole v. McClintock, 999 F.2d 1430, 1433-34 (11th Cir. 1993) (holding that district court abused discretion by admitting FDA report of proposed findings, since "Rule 803 makes no exception for tentative or interim reports subject to revision and review").

Although Plaintiff nowhere describes the specific nature of the documents, they do not seem to be FDA reports or findings, and Plaintiff does not claim that they contain any final opinions by the agency. Exhibit A, for example, appears to be a package of information provided to the Gastrointestinal Drugs Advisory Committee Drug Safety and Risk Management Subcommittee to discuss whether Lotronex® should be returned to the market. Exhibits B and C also do not appear to be FDA findings or reports. The documents seem to be primarily compilations of information or recommendations submitted by outsiders to the FDA, including adverse event reports, rather than conclusions made by the FDA.

Consequently, the reliability justification for agency reports does not apply here to exclude the documents from the realm of inadmissible hearsay. See Id. (quoting Brown v. Sierra

Nevada Mem. Miners Hosp., 849 F.2d 1186, 1189-90 (9th Cir. 1988)) ("The assumption 'that a government agency's findings may be assumed to be trustworthy . . . has substantially diminished force when extended to the sources outside the investigative agency from which the agency culls the information for its report."); Golod v. La Roche, 964 F. Supp. 841, 855 (S.D.N.Y. 1997) (noting that adverse event reports are likely inadmissible hearsay to establish causation); Wade-Greaux v. Whitehall Laboratories, 874 F. Supp. 1441, 1481 (D.V.I. 1994) (noting that event reports may not be sufficiently reliable or relevant to be admissible on the issue of causation). Plaintiff's reliance on Sabel v. Mead Johnson & Co., 737 F. Supp. 135 (D. Mass. 1990), is, therefore, inapposite since the letter at issue in Sabel was "expressed as a final opinion of the FDA, rather than a tentative conclusion" of the doctor that wrote the letter. Id. at 142. Accordingly, Plaintiff's Exhibits A, B, and C are inadmissible.

III. New Jersey Products Liability Act

GSK argues that Plaintiff's common law product liability claims are subsumed by the New Jersey Product Liability Act ("NJPLA"), N.J.S.A. 2A:58C-1 et seq.[4] Plaintiff does not oppose

[4] N.J.S.A. 2A:58C-2 provides:
A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it:
a. deviated from the design specifications, formulae,

GSK's argument.

The Third Circuit has held that the Act is the "sole basis of relief under New Jersey law available to consumers injured by a defective product." Port Authority of New York and New Jersey v. Arcadian Corp., 189 F.3d 305, 313 (3d Cir. 1999) (quoting Repola v. Morbark Indus., Inc., 934 F.2d 483, 492 (3d Cir. 1991)). Accordingly, Plaintiff is limited to claims authorized by the NJPLA, in this case, her claims of design defect and failure to warn.

III. Failure to Warn

Plaintiff claims that GSK neglected to adequately warn consumers of Lotronex®'s dangerous propensities. GSK contends that Plaintiff neither established causation nor specified any actual defect in the warning.

A. Learned Intermediary

GSK argues that the learned intermediary doctrine governs Plaintiff's failure to warn claims. The learned intermediary doctrine authorizes pharmaceutical manufacturers to discharge the duty to warn consumers by supplying physicians with the necessary information regarding a drug's dangerous propensities. Niemiera v. Schneider, 114 N.J. 550, 559 (1989) (opining that as the

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or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

intermediary between the manufacturer and consumer, the prescribing physician can be expected to give the correct and necessary medical advice). Under this rule, the pharmaceutical manufacturer is relieved of the duty to directly convey information to consumers, and is liable only for the failure to warn physicians.

Plaintiff argues that Lotronex® falls within the direct marketing exception to the learned intermediary doctrine, expressed by the New Jersey Supreme Court in Perez v. Wyeth Laboratories, Inc., 161 N.J. 1 (1999). In Perez, the Court revised the doctrine to conform with more contemporary models of health care and increasingly aggressive consumer marketing. The Court reversed a trial court holding that the learned intermediary doctrine applies "even when a manufacturer advertises directly to the public, and a woman is influenced by the advertising campaign," Id. at 7, and found instead that "a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product" has a duty to warn consumers "of the dangers of side effects of the product," Id. at 5.

The Perez defendants argued that the Court should have abstained from deciding whether there is a direct advertising exception to the learned intermediary rule because the plaintiffs did not state whether they had actually been influenced by defective advertising. The Court nonetheless opted to tackle the

learned intermediary question out of efficiency and fairness concerns. However, the Court acknowledged that "[t]he issue on remand will be whether, on a summary judgment motion, there is sufficient evidence for a reasonable jury to determine in the cases of the . . . plaintiffs, that the absence of information or presence of misinformation in [the drug] advertising was . . . a substantial factor in bringing about the harm suffered."[5] Id. at 26.

Plaintiff testified that she was not exposed to any Lotronex® advertising during the time she was ingesting the medication. (Pl.'s Dep. at 107, Def.'s Reply, Ex. A.) Nor had she heard of Lotronex® before beginning the prescription. Id. Because she provided no evidence indicating that she was affected by any advertising or direct consumer marketing, including the GSK website, no reasonable jury could find that consumer advertising for Lotronex® was even a remote factor in bringing about Plaintiff's harm.

B. Inadequate Warning to Physician

Plaintiff argues that GSK neglected to adequately warn Dr. Krachman of Lotronex®'s potentially adverse effects. Defendant

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[5] The Court did not explain whether such a failure to show actual influence from direct advertising would serve to circumvent the newly articulated exception to the learned intermediary doctrine or whether it would merely defeat causation. Regardless, it is clear that a plaintiff who has never seen any advertising cannot be harmed by flaws in that advertising.

argues that Plaintiff does not articulate any defect in the Lotronex® warning, and that no evidence suggests that a warning without the defect would have prevented Plaintiff's injury.

To survive summary judgment, the plaintiff must produce evidence sufficient to enable a reasonable jury to find causation. Fedorczyk v. Caribbean Cruise Lines, Ltd., 82 F.3d 69 (3d Cir. 1996) (affirming summary judgment for failure to establish causation). In the context of a failure to warn claim, the plaintiff must point to facts indicating that "the absence of a warning was a proximate cause of his harm." Coffman v. Keene Corp., 133 N.J. 581, 594 (1993); see also Shelcusky v. Garjulio, 172 N.J. 185, 206 (2002) (holding that while "ordinarily, the jury considers issues of proximate cause," "courts may resolve for themselves the question of legal or proximate causation if they conclude that no reasonable jury could find such causation on the record presented.").

In Strumph v. Schering Corp., 133 N.J. 33 (1993), a pharmaceutical liability case similar to the one presently before the court, the New Jersey Supreme Court determined that the trial court properly granted summary judgment to the drug manufacturer on the basis of plaintiff's failure to demonstrate that an adequate warning would have prevented her harm. The Court adopted the reasoning of Appellate Division Judge Skillman's dissent, holding that where plaintiff's doctors already knew of the drug's

potential hazards, the doctors did not read drug company warnings, and the allegedly absent information would not have affected the doctor's decision to prescribe the medication, there was no "evidence from which a jury could reasonably find that the alleged inadequacy of defendant's warnings regarding [the drug] affected the decision of plaintiff's doctors to prescribe the drug for plaintiff." Strumph v. Schering Corp., 256 N.J. Super. 309, 328 (App. Div. 1992) (Skillman, J.A.D., dissenting).

Here there is every indication that Plaintiff's doctor, Dr. Krachman, did not read package inserts or listen to drug representatives, and that he already knew of Lotronex®'s potential side effects, including constipation and related issues, without reading the warnings. (Krachman Dep. at 25-27.) Dr. Krachman further testified that he instructed patients to call the office if they experienced any complications including constipation, and that he would stop the medicine whenever a plaintiff would contact his office with such a complaint.[6] (Krachman Dep. at 43, 65-66.) Also compelling is Dr. Krachman's testimony that he would continue to prescribe the medication at the time of his deposition, well after Lotronex® was temporarily

[6] Plaintiff's Statement of Facts states that she suffered abdominal pain and constipation, which she treated with over-the-counter remedies. However, there appears to be no evidence in the record supporting this assertion and Plaintiff cites only to the deposition of Dr. Krachman without providing a page or line number.

removed from the market. (Krachman Dep. at 37-38, 99-100.)

Plaintiff provided no evidence that would permit a reasonable jury to find that deficient warnings proximately caused her alleged injury. To the contrary, all evidence indicates that the harm would have occurred regardless of any warnings. Accordingly, Defendant is entitled to summary judgment on Plaintiff's fail to warn claim.[7]

IV. Design Defect

A successful design defect claim under the New Jersey Products Liability Act requires "that the product was defective, that the defect existed when the product left the defendant's control, and that the defect caused injury to a reasonably foreseeable user." Ortiz v. Yale Materials Handling Corp., 2005 WL 2044923, *2 (D.N.J. 2005) (citing Milanowicz v. The Raymond Corp., 148 F. Supp. 2d 525, 528 (D.N.J. 2001)). GSK moves for summary judgment on Plaintiff's allegations of a design defect on the basis that Plaintiff provided no admissible evidence that the drug was defective.

To establish a design defect at the summary judgment stage, a plaintiff must provide sufficient evidence such that a

[7] GSK also argues that Plaintiff has not pointed to any specific defects in the warnings and that Plaintiff's reliance upon the "revised warnings" as "the best evidence of the failure to warn," (Pl.'s Opp. at 10.), is misplaced since the evidence is an inadmissible subsequent remedial measure under Federal Rule of Evidence 407. Because Plaintiff has entirely failed to establish causation, however, the Court will not address these arguments.

reasonable jury could find "either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." Lewis v. American Cyanamid Co., 155 N.J. 544, 570 (1998). The plaintiff thus bears a burden to demonstrate "under a risk-utility analysis the existence of an alternative design that is both practical and feasible." Id. at 571.

New Jersey courts have articulated a seven factor test to evaluate risk-utility, however, "the prevalent view is that, unless one or more of the other factors might be relevant in a particular case, the issue upon which most claims will turn is the proof by plaintiff of a 'reasonable alternative design . . . the omission . . . [of which] renders the product not reasonably safe." Cavanaugh v. Skil Corp., 164 N.J. 1, 8 (2000) (quoting Green v. General Motors Corp., 310 N.J. Super. 507, 517-18 (App. Div. 1998).[8] Courts have further indicated that the only

[8] The seven factors, articulated by the New Jersey Supreme Court in O'Brien v. Muskin Corp., 94 N.J. 169 (1983), are:

1. The usefulness and desirability of the product--its utility to the user and to the public as a whole.
2. The safety aspects of the product--the likelihood that it will cause injury, and the probable seriousness of the injury.
3. The availability of a substitute product [that] would meet the need and not be as unsafe.
4. The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
5. The user's ability to avoid danger by the exercise

situation justifying a finding of design defect in the absence of an alternative design is a showing that "the product is 'so dangerous and of such little use that under the risk-utility analysis [the] manufacturer [should] bear the cost of liability to others.'" Smith v. Keller Ladder Co., 275 N.J. Super. 280, 283-84 (App. Div. 1994) (quoting O'Brien v. Muskin Corp., 94 N.J. at 184); see also Truchan v. Nissan Motor Corp. in U.S.A., 316 N.J. Super. 554, 563-64 (App. Div. 1998) ("[A] risk-utility analysis ordinarily involves 'the consideration of other alternatives.'"). Furthermore, "[w]here the allegedly defective product involves a complex instrumentality, a plaintiff is required to provide expert testimony," since "[e]xpert testimony is necessary to assist the fact finder in understanding 'the mechanical intricacies of the instrumentality.'" Ortiz, 2005 WL 2044923, *2 (quoting Lauder v. Teaneck Volunteer Ambulance Corps, 368 N.J. Super. 320, 331 (App. Div. 2004).

Plaintiff has presented no alternative design, nor any expert testimony suggesting the existence of a practical and

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of care in the use of the product.

6. The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product or of the existence of suitable warnings or instructions.

7. The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Id. at 182.

feasible alternate design. Consequently, Plaintiff must provide evidence such that a reasonable jury could find that Lotronex® is "so dangerous and of such little use" that the cost of liability should rest on GSK. Plaintiff has not done so.

Although Plaintiff's half-page response does not cite to any evidence, Plaintiff appears to be relying on various FDA documents cited in her Statement of Facts and submitted as Exhibits A, B, and C, which recite adverse event reports and non-FDA laboratory results. Not only are these documents inadmissible as unauthenticated hearsay, as discussed previously, Plaintiff provides no expert testimony, including explanation or interpretation of the information contained in the FDA documents, such that a reasonable juror could make use of this evidence.[9] Without an expert, it is impossible to evaluate the evidence to ascertain whether the risk of Lotronex® sufficiently outweighs its benefit, particularly since it appears that the FDA examined the same evidence and determined that Lotronex® should be

[9] Plaintiff does attach an expert report as Exhibit L to the certification of Michael J. Pender, but nowhere cites to the report in her opposition, leaving it to the imagination of the Court to ascertain whether and how this report supports Plaintiff's claim. See Orr v. Bank of America, NT & SA, 285 F.3d 764, 774-75 (9th Cir. 2002) (holding that party's failure to cite page and line numbers when referencing the deposition "alone warrants exclusion of the evidence"; Huey v. UPS, Inc., 165 F.3d 1084, 1085 (7th Cir. 1999) ("[J]udges need not paw over the files without assistance from the parties."); Nissho-Iwai Am. Corp. v. Kline, 845 F.2d 1300, 1307 (5th Cir. 1988) (parties must designate specific facts and their location in the record when relying on deposition testimony).

returned to the market, albeit in a heavily regulated and limited capacity.

Plaintiff has not provided evidence such that a reasonable juror could find that the product is dangerous or of little use, thereby entitling GSK to summary judgment on Plaintiff's design defect claim. See Ortiz, 2005 WL 2044923, *2 (granting summary judgment due to plaintiff's failure to provide admissible expert testimony).

The accompanying Order shall issue today.

Dated: 12-13-05 S/Robert B. Kugler
ROBERT B. KUGLER
United States District Judge